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## SELF CLOSING TISSUE FASTENER

## PRIORITY

This application claims the benefit of the priority of U.S. provisional application 60/785,830, filed Mar. 25, 2006, which is hereby incorporated in its entirety by reference where permitted.

## FIELD OF THE INVENTION

The present invention relates generally to medical apparatus and methods for securing tissue. More particularly, the present invention describes a unique self closing tissue fastener, which is a device for securing or closing of surgically altered tissue, where the device is itself self closing in nature. The device comprises a central ring to which both tissue-piercing members and stabilizing members are affixed. The stabilizing members allow the device to be stored in its activated state on the inside of a tube. As a result, the fastener delivery apparatus can provide an unobstructed, preferably sealed, working access channel through which other surgical instruments, devices and apparatus, for diagnosis or for the control, closure or manipulation of tissue, may be delivered to the surgical site. In particular, a fastener can be delivered to a site under endoscopic observation.

## BACKGROUND OF THE INVENTION

There are many techniques employed to close, secure or lock tissue into a preferred configuration. These techniques include suturing, stapling, taping and the like. Selection of which technique to employ depends upon the type of tissue being repaired, the tissue location, and the required strength of the repair.

The following U.S. patents are representative of the state of the art in the general field of tissue fastener, staple, clip fastener and closure delivery apparatus technology and designs, which now are commonly used in numerous surgical procedures to close or lock tissue apertures, incisions, and the like:

U.S. Pat. No. 7,112,214 Peterson et al.; U.S. Pat. No. 7,001,398 Carley et al.; U.S. Pat. No. 7,692,731 Coleman et al.; U.S. Pat. No. 6,746,460, Gannoe et al.; U.S. Pat. No. 6,623,510, Carley et al.; U.S. Pat. No. 5,667,527, Cook; U.S. Pat. No. 6,149,658, Remiszewski et al.; U.S. Pat. No. 6,491,707 Makower et al.; U.S. Pat. No. 6,884,248 Bolduc et al.; U.S. Pat. No. 6,572,587 Lerman et al.; U.S. Pat. No. 5,772,668 Summers et al.; and U.S. Pat. No. 6,913,607 Ainsworth et al.

Many conventional surgical fasteners have been in the form of ordinary metal staples, which are bent by the delivery apparatus to hook together body tissue. Typically, conventional staples comprise a pair of legs joined together at one end by a crown. The crown may be a straight member connecting the legs or may form an apex. Moreover, the legs may extend substantially perpendicular from the crown or at some angle. Irrespective of the particular configuration, however, conventional staples are designed so that they may be deformed to hold body tissue.

Accordingly, the stapler applicators have conventionally embodied structure functioning to project the conventional staple into tissue as well as to deform the staple so that it is retained against the tissue. Such applicators as described by U.S. Pat. No. 6,446,854, Remiszewski et al., include an anvil cooperating with means to eject the conventional staple from the applicator. In some applications, access to the body tissue from two opposite directions is available and the anvil can

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operate to deform the legs of the staple after they have passed through the body tissue. In applications where access to the tissue is from only one direction, the anvil may deform the crown of the conventional staple so that its legs will project into the body tissue in a fashion so as to hold the staple against the tissue.

U.S. Pat. No. 6,884,248 Bolduc, et al., represents a class of spring like coil devices typically helical in design which can be driven rotationally in a corkscrew like manner to thread the fastener article into the tissue. This patent further describes both single and double embodiments of this device design such as coil-like devices which can be screwed into tissue to fasten it. In order to close tissue tightly, the fastener typically must have a portion of the coil configured to provide a gathering and tightening of the tissue as it is driven. Thus by design, to accomplish the goal of locking tissue the embodiment is typically configured as a spiral helical shape where the pitch and diameter are continuously shrinking. Furthermore, for the helical spiral design to be driven requires a tab or locking member to engage the driving shaft. Such features typically occlude the central portion of the fastener given the need for a large to small diameter taper of the fastener, thereby making the passage of surgical implements through the delivery system very difficult.

When the goal of the surgeon is securing or locking tissue to generate an annular port-like geometry, or a passageway, then, like the staple and classic suturing methods known in the art, the helical fastener will also require multiple deployments spaced in a circular pattern about the area to be secured. All such multiple deployment methods are time consuming and difficult to execute via typical ported access multifunctional surgical procedures.

A newer technology for fastening tissue is described in a series of patents to Carley and coworkers, for example U.S. Pat. No. 7,001,398 Carley et al., and U.S. Pat. No. 6,623,510 Carley et al. These novel fasteners represent a class of annular serpentine looped spring like devices which are essentially planar at rest and annular in a defined "transverse configuration" which is used for the delivery of the device to the surgical site.

These embodiments are comprised of a uniform geometrical backbone portion having a continuous serpentine path of looped elements which are generally symmetrical in construct and geometrical relation. Barbs are attached to some of these serpentine elements, and project inward in the relaxed planar state. They are activated by insertion of a central stabilizing core, forcing the devices from a planar arrangement to an annular configuration. The annular configuration is unstable without the central core. Upon removal of the central stabilizing core, the device folds back to the original configuration, gathering tissue that lies under its pointed projections.

A drawback of these devices is that the symmetrical composition of serpentine features and their location are only stable while a solid core is inserted through the center of the planar object to make the transverse form. If the devices are inserted on the inside of a tube in the transverse configuration, the tips of the barbs will rotate inwards to meet in the center of the tube, or to meet the tube walls, thus obstructing the tube and perhaps preventing proper delivery. The requirement for maintenance of a central internal core element within the delivery system to hold and maintain the embodiment in the transverse position, to stabilize and manage the device overall annular size and annular condition, prevents the passage of other instruments through the central core of the tissue fastening device while a fastener is in place for delivery. Thus, it is very difficult with the Carley device to deliver a tissue fastener, whether from the outside of a stabilizing core or of a